REMARKS

Status of the Claims

Claims 1-4, 17-19 and 21-36 are now present in this application. Claims 1-4, 17, 19 and 21-23 stand withdrawn, as being drawn to nonelected subject matter.

Reconsideration of this application, in view of the remarks below, is respectfully requested.

Request for Entry of Response After Final Rejection

This response should be entered after final rejection because it is believed to place the application in condition for allowance.

In the event that the Examiner disagrees and finds that this response does not place this application into condition for allowance, the Examiner is requested to enter this response because it places the application into better condition for appeal.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 27 and 28 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject mater which applicant regards as the invention. Applicants respectfully traverse this rejection.

One of ordinary skill in the art would understand what degree of dissolution encompassed by "essentially completely" dissolved, as recited in the claims. For example in the CRC Handbook of Chemistry and Physics 62nd Edition (1981-1982), the Table of Physical Constants of Organic Compounds includes a column entitled "Solubility" which lists solvents that dissolve a particular organic compound. At page C-61 (attached), it is explained that the solvents entered in this column "in medium type means soluble; entries in boldface mean very soluble." The authors of the CRC recognize that one of skill in the art can distinguish between the meaning of "soluble" and "very soluble," and one of skill in the art would similarly understand the meaning of the recitation in the claims that an extract of dried amla fruit is capable of being essentially completely dissolved in an aqueous solution.

In view of the discussion above, Applicants respectfully request that the rejection of claims 27 and 28 under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 18 and 24-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the English translation of Liu et al., Chinese Patent Application Publication No. 1278433 (hereinafter "Liu") in view of Bordia *et al.*, "Comparative effect of vitamin C, amla juice and amla pulp on blood lipids, platelet aggregation and experimental atheroma in rabbits," Indian Heart J., 1985, Vol. 37, No. 3, pages 179-82 (hereinafter "Bordia"). Claims 27 and 28 have been cancelled and their rejection is moot. The rejection of claims 18, 24-26 and 29-36 is respectfully traversed.

When determining whether a claim is obvious, an examiner must make "a searching comparison of the claimed invention including all its limitations with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (*citing In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

The claimed methods comprise administering a composition comprising an extract of dried amla fruit to a patient to inhibit fibrin formation. Liu and Bordia taken alone or together do not teach methods of inhibiting fibrin formation by administering an extract of dried amla fruit, as in the claimed invention.

It is alleged at page 3 of the Office Action that "[Liu's] extract inhibits fibrin formation (see page 4 of the translation)." Applicants respectfully disagree with this allegation.

Liu discloses extracts of dried amla leaves extracted using alcohol or acetone at room temperature (Liu's Application Example 11). Liu's amla leaf extracts exhibit thrombolytic (dissolves blood clots) activity. In contrast, the claimed methods comprise administering an extract of dried amla fruit, which acts as an inhibitor of fibrin (fibrous protein involved in the clotting of blood) formation. That is, fruit extracts of the claimed invention inhibit the formation of a thrombus (blood clot), while Liu's leaf extracts exhibit thrombolytic activity after a

thrombus has formed. One of ordinary skill in the art would recognize that these two types of activity are quite different from each other (one before a thrombus is formed and one after a thrombus has formed).

As with Liu, Bordia fails to disclose an inhibitor of fibrin formation. Bordia also fails to teach the preparation of an extract from dried amla fruit. That is, Bordia discloses the use of amla juice and amla pulp, not an extract from dried amla fruit, as in the claimed invention.

It is asserted at page 4 of the Office Action that "[e]nhanced fibrinolysis would lead to an inhibition in fibrin formation." Applicants respectfully disagree with this assertion. Indeed, one of ordinary skill in the art recognizes that fibrinolysis is different from inhibiting fibrin formation. That is, fibrin formation and enhanced fibrinolysis of formed fibrin are quite different activities. Applicants respectfully refer the Examiner to the discussion below and to paragraphs [0010] – [0012] of the present specification (summarized below) regarding this distinction.

Fibrin, a filamentous protein, is formed by the action of thrombin on fibrinogen. The conversion of fibrinogen to fibrin is the third and final stage of blood clotting. The fibrin is deposited as fine interlacing filaments which entangle red and white blood cells and platelets, the whole forming a clot (Taber's Cyclopedic Medical Dictionary, Edition 20, 2005, Venes Ed., page 794).

Blood clotting can be described as occurring by two pathways, depending on the beginning of the process, extrinsic coagulation and intrinsic coagulation. The extrinsic coagulation pathway requires the blood to be exposed to subendothelial tissue factor originating outside the blood. The intrinsic coagulation pathway occurs when blood is exposed to a foreign surface (*i.e.*, when blood is drawn) and factor XII is activated. The clotting pathway whether triggered by exposure to subendothelial tissue factor or factor XII activation ultimately causes a cascade of chemical reactions that ultimately result in conversion of prothrombin to thrombin, thrombin to fibrinogen and fibrinogen to fibrin. (Taber's Cyclopedic Medical Dictionary, Edition 20, 2005, Venes Ed., page 436-437.) Compositions of the claimed invention inhibit fibrin formation, and therefore, inhibit formation of a blood clot.

After a clot is formed, fibrinolysis is a process whereby the clot is broken down (http://en.wikipedia.org/wiki/Fibrinolysis, enclosed). In fibrinolysis, plasmin enzyme cuts the fibrin mesh at various places within the blood clot, leading to the production of circulating

fragments that are cleared by other proteases. Thus, fibrinolysis involves cleavage of formed fibrin. Thrombolysis is the breakdown of a blood clots by pharmacological means and works by stimulating fibrinolysis by plasmin through analogs of tissue plasminogen activator.

The present Specification (paragraphs [0010] – [0012]) discloses that antithrombotic agents include anti-platelet agents and anti-coagulants. Anti-platelet agents inhibit the function of platelets involved in the early stages of thrombus formation. Aspirin is one among many drugs that has been developed for use in preventing formation of blood clots. Heparin and warfarin are examples of anti-coagulants known in the art, which act by promoting inhibition of thrombin.

In contrast to antithrombotic agents that prevent clots from forming, thrombolytic agents cause existing clots to be broken up. Plasminogen activators, such as streptokinase or urokinase, are known as thrombolytic agents. Existing therapeutic methods involve intravenous injection of a thrombolytic agent into a patient with a formed thrombus to activate the patient's own thrombolytic system to break up an existing blood clot. Thus, the present Specification discloses that therapeutic agents inhibiting the formation of fibrin/clots are different from those involved in breaking up existing clots (thrombolysis or fibrinolysis).

Liu and Bordia taken alone or together do not teach methods of inhibiting fibrin formation by administering an extract of dried amla fruit, as in the claimed invention. In view of the discussion above, Applicants respectfully request that the rejection of claims 18, 24-26 and 29-36 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Stephanie A. Wardwell, Ph.D., Registration No. 48,025 at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

By 

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Attachments: CRC Handbook of Chemistry and Physics, 62nd Edition, 1981-1982, Weast Ed., CRC Press Inc., Boca Raton, FL, page C-61.
Taber's Cyclopedic Medical Dictionary, Edition 20, 2005, Venes Ed., pages 436-437 and 794.
http://en.wikipedia.org/wiki/Fibrinolysis
http://en.wikipedia.org/wiki/Thrombolysis